

**§ 556.750 Virginiamycin.**

(a) *Acceptable daily intake (ADI)*. The ADI for total residues of virginiamycin is 250 micrograms per kilogram of body weight per day.

(b) *Tolerances*—(1) *Swine*. Tolerances are established for residues of virginiamycin in uncooked edible tissues of 0.4 part per million (ppm) in kidney, skin, and fat, 0.3 ppm in liver, and 0.1 ppm in muscle.

(2) *Broiler chickens and cattle*. A tolerance for residues of virginiamycin is not required.

[64 FR 48296, Sept. 3, 1999]

**§ 556.760 Zeranol.**

(a) *Acceptable daily intake (ADI)*. The ADI for total residues of zeranol is 0.00125 milligrams per kilogram of body weight per day.

(b) *Tolerances*. The tolerances for residues of zeranol in edible tissues are:

(1) *Cattle*. A tolerance is not needed.

(2) *Sheep*. 20 parts per billion.

(c) *Related conditions of use*. See § 522.2680 of this chapter.

[40 FR 13942, Mar. 27, 1975, as amended at 54 FR 31950, Aug. 3, 1989; 67 FR 6867, Feb. 14, 2002; 70 FR 15759, Mar. 29, 2005]

**§ 556.770 Zoalene.**

Tolerances are established for residues of zoalene (3,5-dinitro-*o*-toluamide) and its metabolite 3-amino-5-nitro-*o*-toluamide in food as follows:

(a) In edible tissues of chickens:

(1) 6 parts per million in uncooked liver and kidney.

(2) 3 parts per million in uncooked muscle tissue.

(3) 2 parts per million in uncooked fat.

(b) In edible tissues of turkeys: 3 parts per million in uncooked muscle tissue and liver.

## **PART 558—NEW ANIMAL DRUGS FOR USE IN ANIMAL FEEDS**

### **Subpart A—General Provisions**

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### **Subpart B—Specific New Animal Drugs For Use in Animal Feeds**

558.35 Aklomide.

558.55 Amprolium.

558.58 Amprolium and ethopabate.

558.59 Apramycin.

558.60 Arsanilate sodium.

558.62 Arsanilic acid.

558.76 Bacitracin methylene disalicylate.

558.78 Bacitracin zinc.

558.95 Bambermycins.

558.105 [Reserved]

558.115 Carbadox.

558.120 Carbarsone (not U.S.P.).

558.128 Chlortetracycline.

558.140 Chlortetracycline and sulfamethazine.

558.145 Chlortetracycline, procaine penicillin, and sulfamethazine.

558.155 Chlortetracycline, sulfathiazole, penicillin.

558.175 Clopidol.

558.185 Coumaphos.

558.195 Decoquinate.

558.198 Diclazuril.

558.205 Dichlorvos.

558.235 Efrotomycin.

558.248 Erythromycin thiocyanate.

558.254 Famphur.

558.258 Fenbendazole.

558.265 Halofuginone hydrobromide.

558.274 Hygromycin B.

558.295 Iodinated casein.

558.300 Ivermectin.

558.305 Laidlomycin.

558.311 Lasalocid.

558.315 Levamisole hydrochloride (equivalent).

558.325 Lincomycin.

558.340 Maduramicin ammonium.

558.342 Melengestrol.

558.348 Mibolerone.

558.355 Monensin.

558.360 Morantel tartrate.

558.363 Narasin.

558.364 Neomycin sulfate.

558.365 Nequinat.

558.366 Nicarbazine.

558.369 Nitarsone.

558.376 Nitromide and sulfanitran.

558.415 Novobiocin.

558.430 Nystatin.

558.435 Oleandomycin.

558.450 Oxytetracycline.

558.460 Penicillin.

558.464 Poloxalene.

558.465 Poloxalene free-choice liquid Type C feed.

558.485 Pyrantel tartrate.

558.500 Ractopamine.

558.515 Robenidine hydrochloride.

558.530 Roxarsone.

### § 558.3

### 21 CFR Ch. I (4–1–05 Edition)

558.550	Salinomycin.
558.555	Semduramicin.
558.575	Sulfadimethoxine, ormetoprim.
558.579	Sulfaethoxypyridazine.
558.582	Sulfamerazine.
558.586	Sulfaquinoxaline.
558.600	Tiamulin.
558.615	Thiabendazole.
558.618	Tilmicosin.
558.625	Tylosin.
558.630	Tylosin and sulfamethazine.
558.635	Virginiamycin.
558.680	Zoalene.

AUTHORITY: 21 U.S.C. 360b, 371.

SOURCE: 40 FR 13959, Mar. 27, 1975, unless otherwise noted.

#### Subpart A—General Provisions

#### § 558.3 Definitions and general considerations applicable to this part.

(a) Regulations in this part provide for approved uses of drugs and combinations of drugs in animal feeds. Approved combinations of such drugs are specifically identified or incorporated by cross-reference. Unless specifically provided for by the regulations, a combination of two or more drugs is not approved.

(b) The following definitions apply to terms used in this part:

(1) New animal drugs approved for use in animal feed are placed in two categories as follows:

(i) Category I—These drugs require no withdrawal period at the lowest use level in each species for which they are approved.

(ii) Category II—These drugs require a withdrawal period at the lowest use level for at least one species for which they are approved, or are regulated on a “no-residue” basis or with a zero tolerance because of a carcinogenic concern regardless of whether a withdrawal period is required, or are a veterinary feed directive drug.

(2) A “Type A medicated article” is intended solely for use in the manufacture of another Type A medicated article or a Type B or Type C medicated feed. It consists of a new animal drug(s), with or without carrier (e.g., calcium carbonate, rice hull, corn, gluten) with or without inactive ingredients. The manufacture of a Type A medicated article requires an application approved under § 514.105 of this chapter.

(3) A “Type B medicated feed” is intended solely for the manufacture of other medicated feeds (Type B or Type C). It contains a substantial quantity of nutrients including vitamins and/or minerals and/or other nutritional ingredients in an amount not less than 25 percent of the weight. It is manufactured by diluting a Type A medicated article or another Type B medicated feed. The maximum concentration of animal drug(s) in a Type B medicated feed is 200 times the highest continuous use level for Category I drugs and 100 times the highest continuous use level for Category II drugs. The term “highest continuous use level” means the highest dosage at which the drug is approved for continuous use (14 days or more), or, if the drug is not approved for continuous use, it means the highest level used for disease prevention or control. If the drug is approved for multiple species at different use levels, the highest approved level of use would govern under this definition. The manufacture of a Type B medicated feed from a Category II, Type A medicated article requires a medicated feed mill license application approved under § 515.20 of this chapter.

(4) A “Type C medicated feed” is intended as the complete feed for the animal or may be fed “top dressed” (added on top of usual ration) on or offered “free-choice” (e.g., supplement) in conjunction with other animal feed. It contains a substantial quantity of nutrients including vitamins, minerals, and/or other nutritional ingredients. It is manufactured by diluting a Type A medicated article or a Type B medicated feed. A Type C medicated feed may be further diluted to produce another Type C medicated feed. The manufacture of a Type C medicated feed from a Category II, Type A medicated article requires a medicated feed mill license application approved under § 515.20 of this chapter.

(5) A Type B or Type C medicated feed manufactured from a drug component (bulk or “drum-run” (dried crude fermentation product)) requires an application approved under § 514.105 of this chapter.

(6) A “veterinary feed directive (VFD) drug” is a new animal drug approved under section 512(b) of the Federal Food, Drug, and Cosmetic Act (the act) for use in or on animal feed. Use of a VFD drug must be under the professional supervision of a licensed veterinarian.

(7) A “veterinary feed directive” is a written statement issued by a licensed veterinarian in the course of the veterinarian’s professional practice that orders the use of a veterinary feed directive (VFD) drug in or on an animal feed. This written statement authorizes the client (the owner of the animal or animals or other caretaker) to obtain and use the VFD drug in or on an animal feed to treat the client’s animals only in accordance with the directions for use approved by the Food and Drug Administration (FDA). A veterinarian may issue a VFD only if a valid veterinarian-client-patient relationship exists, as defined in § 530.3(i) of this chapter.

(8) A “medicated feed” means a Type B medicated feed as defined in paragraph (b)(3) of this section or a Type C medicated feed as defined in paragraph (b)(4) of this section.

(9) For the purposes of this part, a “distributor” means any person who distributes a medicated feed containing a VFD drug to another distributor or to the client-recipient of the VFD.

(10) An “animal production facility” is a location where animals are raised for any purpose, but does not include the specific location where medicated feed is made.

(11) An “acknowledgment letter” is a written communication provided to a distributor by a consignee who is not

the ultimate user of medicated feed containing a VFD drug. An acknowledgment letter affirms that the consignee will not ship such medicated animal feed to an animal production facility that does not have a VFD, and will not ship such feed to another distributor without receiving a similar written acknowledgment letter.

[51 FR 7392, Mar. 3, 1986, as amended at 52 FR 2682, Jan. 26, 1987; 54 FR 51386, Dec. 15, 1989; 56 FR 19268, Apr. 26, 1991; 64 FR 63206, Nov. 19, 1999; 65 FR 76929, Dec. 8, 2000]

#### § 558.4 Requirement of a medicated feed mill license.

(a) A feed manufacturing facility must possess a medicated feed mill license in order to manufacture a Type B or Type C medicated feed from a Category II, Type A medicated article.

(b) The manufacture of the following types of feed are exempt from the required license, unless otherwise specified:

(1) Type B or Type C medicated feed using Category I, Type A medicated articles or Category I, Type B or Type C medicated feeds; and

(2) Type B or Type C medicated feed using Category II, Type B or Type C medicated feeds.

(c) The use of Type B and Type C medicated feeds shall also conform to the conditions of use provided for in subpart B of this part and in §§ 510.515 and 558.15 of this chapter.

(d) This paragraph identifies each drug by category, the maximum level of drug in Type B medicated feeds, and the assay limits for the drug in Type A medicated articles and Type B and Type C medicated feeds, as follows:

#### CATEGORY I

Drug	Assay limits percent <sup>1</sup> type A	Type B maximum (200x)	Assay limits percent <sup>1</sup> type B/C <sup>2</sup>
Aklomide .....	90–110	22.75 g/lb (5.0%) .....	85–120.
Amprolium with Ethopabate .....	94–114	22.75 g/lb (5.0%) .....	80–120.
Bacitracin methylene disalicylate .....	85–115	25.0 g/lb (5.5%) .....	70–130.
Bacitracin zinc .....	84–115	5.0 g/lb (1.1%) .....	70–130.
Bambermycins .....	90–110	800 g/ton (0.09%) .....	80–120/70–130.
Buquinolate .....	90–110	9.8 g/lb (2.2%) .....	80–120.
Chlortetracycline .....	85–115	40.0 g/lb (8.8%) .....	80–115/70–130.
Coumaphos .....	95–115	6.0 g/lb (1.3%) .....	80–120.
Decoquinolate .....	90–105	2.72 g/lb (0.6%) .....	80–120.
Dichlorvos .....	100–115	33.0 g/lb (7.3%) .....	90–120/80–130.
Diclazuril .....	90–110	182 g/t (0.02%) .....	85–115/70–120.
Efrotomycin .....	94–113	1.45 g/lb (0.32%) .....	80–120.